

**Appl. No.** : 10/830,071  
**Filed** : April 23, 2004

### **REMARKS**

Applicants have hereby canceled Claims 1-9 and 13-17, amended Claims 24 and 41 to correct grammatical errors, and amended Claim 10. Claims 10-12 and 18-43 are pending in the present application. Applicants have carefully considered all of the objections and comments raised by the Examiner in the Office Action of April 13, 2005 and respond to them below.

#### Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-17 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly fails to provide enablement for methods of treating obesity commensurate with the scope of the claims. Applicants have canceled Claims 1-9 and 13-17, and thus the § 112 rejections of these claims are now moot. Claim 8 is directed to a method of reducing the risk of hypertension, diabetes, or dyslipidaemia with zonisamide, and Claims 9 and 10 are directed to methods of treating obesity with zonisamide or a compound of the generic class of compounds that comprises zonisamide. The Examiner acknowledges that the specification is “enabling for treating obesity with ... zonisamide,” and that “it is well established ... that a method of reducing the risk of developing diabetes, as well as treating diabetes, can be achieved by treating obesity.” Thus, Applicants respectfully submit that the specification is enabling with regard to Claims 8-10, and request withdrawal of the rejections of these Claims under § 112.

#### Rejections under 35 U.S.C. § 102(e)

Claims 1, 4-9, 11-24 and 35-41 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Coffin et al. (U.S. Patent Application No. 2001/0025038). The Examiner asserts that “Coffin et al. teach methods of reducing food cravings in mammals with ... anticonvulsant drugs, namely zonisamide.” Since Applicants have canceled Claims 1-9 and 13-17, the rejection of these Claims under § 102(e) is now moot. With respect to Claims 18-24 and 35-43, Applicants respectfully disagree with the Examiner's characterization of Coffin et al., as described below.

Claims 10-12 and Claims 18-24 and 35-43 are directed to methods of treating obesity and reducing weight, respectively, by administering a composition comprising zonisamide. In contrast, Coffin et al. is directed to a method of reducing cravings for addictive substances by administering an antagonist or partial agonist of D<sub>1</sub> or D<sub>5</sub>-type Dopamine receptors (p. 1, paragraph 15). Coffin et al. does not in any way disclose the use of zonisamide as a weight-loss

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agent. Rather, Coffin et al. discloses the use of zonisamide only in stating that the claimed D<sub>1</sub>/D<sub>5</sub> antagonists/partial agonists may be administered alone or in combination with “other CNS compounds.” In describing such “other CNS compounds,” the specification enumerates a list of over a dozen general classes of compounds as well as approximately fifty specific compounds, only one of which is zonisamide. Zonisamide is not mentioned where the specification describes subsets of the “other CNS compounds” that “modify use or desire to consume food” (p. 4, paragraph 67), or that function as “anti-obesity compounds” (p.4, paragraph 64; p.5, paragraph 73). To the contrary, Zonisamide is referred to only as an anti-convulsant (p. 5, paragraph 78). Thus, Coffin et al. does not disclose the use of zonisamide as a weight loss-promoting agent. Accordingly, applicants respectfully submit that Claims 18-24 and 35-43 are not anticipated by Coffin et al., and request withdrawal of the rejection of these claims under § 102(e).

Rejections under 35 U.S.C. § 103(a)

Claims 1-43 stand rejected under 35 U.S.C. § 103 for allegedly being unpatentable over the disclosure of Ayala or Shank (U.S. Patent No. 6,071,537) in view of Gadde et al. Applicants have canceled Claim 1-9 and 13-17, and thus the § 103 rejections of these claims are now moot. With regard to Claims 10-12 and 18-43, Applicants respectfully disagree with the Examiner’s characterization of the Ayala reference and the Examiner’s application of the Gadde and Shank references. Claims 10-12 and 18-43 are directed to methods comprising the administration of zonisamide or a compound of the generic class of compounds that comprises zonisamide for reducing the risk of hypertension, diabetes, or dyslipidaemia (Claim 10), treating obesity (Claims 11-12), reducing weight (18-26 and 35-43), and treating eating disorders (Claims 27-34). The Examiner alleges that Shank teaches treating obesity with topiramate, and that Gadde et al. teaches the administration of bupropion for the treatment of obesity. Thus, the Shank and Gadde references are not relevant to Claims 10-12 and 18-43. The Examiner alleges that Ayala teaches the administration of zonisamide to achieve weight loss. Applicants respectfully disagree. Rather, Ayala et al. teaches the treatment of epilepsy with zonisamide, and notes that epileptic patients who took zonisamide lost weight in the process. This event is characterized as an “adverse event” and Ayala et al. admonishes practitioners to consider the patient baseline weight before considering them for treatment with zonisamide. Therefore, Ayala et al. considered the loss of weight as something to be avoided, or carefully screened for, as opposed to something to be encouraged. In other words, Ayala et al. teaches away from the use of zonisamide to

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intentionally cause weight loss in individuals. As none of the references cited by the Examiner teach or disclose the use of zonisamide for reducing the risk of hypertension, diabetes, or dyslipidaemia, treating obesity, reducing weight, or treating eating disorders, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103.

Obviousness-type double patenting rejections

Claims 1-43 are provisionally rejected under the doctrine of obviousness-type double patenting over co-pending Application Nos. 10/440,404, 11/058,981, 11/059,027, and 11/034,316. Applicants respectfully request the Examiner to hold the rejection in abeyance until the prosecution of the present application and the aforementioned co-pending applications have progressed further.

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### CONCLUSION

Applicants have canceled Claims 1-9 and 13-17, amended Claim 10, amended Claims 24 and 41 to correct grammatical errors, and have otherwise addressed all of the Examiner's concerns stated in the Office Action of April 13, 2005.

No fee is believed due in connection with this response. If this is incorrect, please charge any required fees, including any extension of time fees, to Deposit Account No. 11-1410. Applicants invite the Examiner to call the undersigned if any issues can be resolved through a telephone conversation.

Respectfully submitted,

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